AF

Attorney Docket No.: 9099-4 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Robert D. Black
Serial No.: 10/005,889
Filed: November 7, 2001
For: CIRCUITS FOR IN VIVO DETECTION OF BIOMOLECULE CONCENTRATIONS USING FLUORESCENT TAGS

Group: 1641
Examiner: Gary W. Counts
Confirmation No.: 7939

November 15, 2006

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TRANSMITTAL OF APPEAL BRIEF
(PATENT APPLICATION--37 C.F.R. § 41.37)

1. Transmitted herewith is the APPEAL BRIEF for the above-identified application, pursuant to the Notice of Appeal filed on June 30, 2006.

2. This application is filed on behalf of
☐ a small entity.

3. Pursuant to 37 C.F.R. § 41.20(b)(2), the fee for filing the Appeal Brief is:

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Respectfully submitted,

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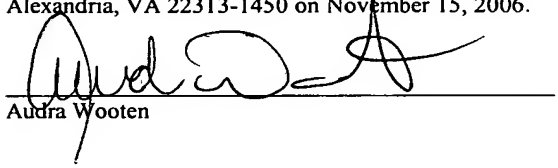

Audra Wooten

Attorney Docket No.: 9099-4 PATENT

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APPELLANT'S BRIEF ON APPEAL UNDER 37 C.F.R. §41.37

Sir:

This Appeal Brief is filed pursuant to the "Notice of Appeal to the Board of Patent Appeals and Interferences" mailed June 30, 2006, and the "Notice of Panel Decision from Pre-Appeal Brief Review" mailed August 15, 2006.

Real Party In Interest

The real party in interest is assignee Sicel Technologies, Inc.

Related Appeals and Interferences

A Notice Of Appeal To The Board Of Patent Appeals And Interferences and a Reasons In Support Of Applicant's Pre-Appeal Brief Request For Review was filed on June 30, 2006, in the present case in response to the Final Office Action mailed March 3, 2006 (hereinafter the "Final Action"). Appellant is aware of no appeals or interferences that would be affected by the present appeal.

Status of Claims

Appellant appeals the final rejection of Claims 8-17, 29-31, 35-37, which as of the filing date of this Brief remain under consideration. The attached Appendix A presents the claims at issue as rejected in the Final Action.

Status of Amendments

All amendments in the present case have been entered.

Summary of the Claimed Subject Matter

The present application includes independent Claim 8, which is a claim to a circuit for detecting biomolecules *in vivo*. Such a circuit can include, in some embodiments according to the invention, an optical radiation source that is configured for *in vivo* use to emit first optical radiation and an optical radiation detector that is configured for *in vivo* use to detect second optical radiation emitted by excited labeled binding molecules. *See specification, for example, page 8, line 32 to page 9, line 27 and page 13, lines 5 to 28.*

Further, the circuit can include a processor circuit that is coupled to the optical radiation source and the optical radiation detector. The processor circuit can be configured to release fluorescently labeled antibodies selected to bind with predetermined Tumor Specific Antigens (TSAs). *See, for example, specification, page 8, lines 24 to 31.*

The processor circuit can be further configured to activate the *in vivo* optical radiation source after a predetermined first time interval after release of the fluorescently labeled antibodies, where the predetermined first time interval is selected to allow a first portion of the fluorescently labeled antibodies to bind with local available TSAs and a second portion of the fluorescently labeled antibodies to become remote from the circuit so that the first optical radiation excites the first portion of the fluorescently labeled antibodies bound with the local available TSAs and does not excite the second portion of the fluorescently labeled antibodies that become remote. *See, for example, specification, page 9, lines 8 to 11 and page 10, lines 4 to 24.*

The processor circuit can be further configured to sense a voltage generated by the *in vivo* optical radiation detector after a second predetermined time interval, the second predetermined time interval being after emission of the first optical radiation has ceased. *See, for example, specification, page 13, lines 33 to 34 and page 10, lines 4 to 24.*

Grounds of Rejection to Be Reviewed on Appeal

1. Claims 8, 15-17, and 29-31, 34, 36, and 37 stand rejected under 35 U.S.C. § 102 over U.S. Patent No. 6,551,838 to Santini, Jr. et al. ("Santini"). *Final Official Action, pages 4 and 6.*[1]

2. Claim 9 stands rejected under 35 U.S.C. § 103 over Santini in view of U.S. Patent Publication No. 2001/0051766 by Gazdzinski or U.S. Patent No. 6,217,869 to Meyer. *Final Official Action, page 5.*

3. Claims 10-13 stand rejected under 35 U.S.C. § 103 over Santini in view of U.S. Patent No. 6,119,031 to Crowley. *Final Official Action, page 5.*

4. Claim 14 stands rejected under 35 U.S.C. § 103 over Santini in view of U.S. Patent Publication No. 2002/0072784 by Sheppard Jr. Et al. *Final Official Action, page 7.*

5. Claim 35 stands rejected under 35 U.S.C. § 103 over Santini in view of U.S. Patent No. 6,491,666 to Santini Jr. *Final Official Action, page8.*

Argument

I. Introduction

Anticipation requires that each and every element of the claim is found in a single prior art reference. *W. L. Gore & Associates Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1554, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1983). Stated another way, all material elements of a claim must be found in one prior art source. *In re Marshall*, 198 U.S.P.Q. 344 (C.C.P.A 1978). "Anticipation under 35 U.S.C. § 102 requires the disclosure in a single piece of prior art of each and every limitation of a claimed invention." *Apple Computer Inc. v. Articulate Systems Inc.* 57 USPQ2d 1057, 1061 (Fed. Cir. 2000). A finding of anticipation further requires that there must be no difference between the claimed invention and the disclosure of the cited reference as viewed by one of ordinary skill in the art. *See Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991).

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[1]Appellant notes that, although the above rejection taken from the Final Action indicates that Claim 34 remains pending, Claim 34 was, in-fact, canceled in Appellant's response dated December 7, 2005.

Additionally, the cited prior art reference must be enabling, thereby placing the allegedly disclosed matter in the possession of the public. *In re Brown*, 329 F.2d 1006, 1011, 141 U.S.P.Q. 245, 249 (C.C.P.A. 1964). Thus, the prior art reference must adequately describe the claimed invention so that a person of ordinary skill in the art could make and use the invention.

Appellant respectfully submits that the pending claims are patentable over the cited reference as Santini fails to disclose all of the recitations of the pending claims, as will be discussed in detail below.

II. The rejection of Claims 8, 15-17, and 29-31, 36, and 37

A. Independent Claim 8 is Patentable

As indicated above, Independent Claim 8 stands rejected under 35 U.S.C. § 102 over Santini. Appellant respectfully submits that Santini does not disclose the recitations of independent Claim 8 in accordance with section 102. In particular, Santini does not disclose:

> A circuit for detecting biomolecules *in vivo*, the circuit comprising
> an optical radiation source configured for *in vivo* use that emits first optical radiation;
> an optical radiation detector configured for *in vivo* use that detects second optical radiation emitted by excited labeled binding molecules; and
> a processor circuit, coupled to the optical radiation source and the optical radiation detector,
> wherein the processor circuit is configured to release fluorescently labeled antibodies selected to bind with predetermined Tumor Specific Antigens (TSAs),
> the processor circuit is further configured to activate the *in vivo* optical radiation source after a predetermined first time interval after release of the fluorescently labeled antibodies, the predetermined first time interval selected to allow a first portion of the fluorescently labeled antibodies to bind with local available TSAs and a second portion of the fluorescently labeled antibodies to become remote from the circuit so that the first optical radiation excites the first portion of the fluorescently labeled antibodies bound with the local available TSAs and does not excite the second portion of the fluorescently labeled antibodies that become remote,
> the processor circuit is further configured to sense a voltage generated by the *in vivo* optical radiation detector after a second predetermined time interval, the second predetermined time interval being after emission of the first optical radiation has ceased.

Santini does not disclose, for example, a processor circuit configured to "release fluorescently labeled antibodies selected to bind with predetermined Tumor Specific Antigens," and "configured to activate the *in vivo* optical radiation source after a predetermined first time interval after release of the fluorescently labeled antibodies", where the "predetermined first time interval [is] selected to allow a first portion of the fluorescently labeled antibodies to bind with local available TSAs and a second portion of the fluorescently labeled antibodies to become remote from the circuit so that the first optical radiation excites the first portion of the fluorescently labeled antibodies bound with the local available TSAs and does not excite the second portion of the fluorescently labeled antibodies that become remote," and "configured to sense a voltage generated by the *in vivo* optical radiation detector after a second predetermined time interval, the second predetermined time interval being after emission of the first optical radiation has ceased" as recited above.

As understood by Appellant, the Final Action does not argue that Santini does not disclose these recitations, but rather bases the rejections on the allegations that the functional recitations on independent Claim 8 cited above do not define a structural difference over the art, as Santini is capable of performing the claimed functions and that, further, the functional recitations are only an "intended use." *Final Official Action, page 4.*

Appellant respectfully submits that the basis for the final rejections is flawed as established case law provides that **a processor that is programmed to provide a particular function is structurally different than other processor circuits that are programmed to provide a different function**. For example, *Application of Noll*, 545 F.2d 141, 148 (CCPA 1976), held that "[t]here is nothing abstract about the claimed invention. It comprises physical structure, including storage devices and electrical components uniquely configured to perform specified functions through the physical properties of electrical circuits to achieve controlled results. **Appellant's programmed machine is structurally different from a machine without that program. (emphasis added).**

Also, *In re Lowry*, 32 F.3d 1579, 1583-84 (Fed. Cir. 1994) held that the programmed operations of a processor defines a structure:

> In Lowry's invention, the stored data adopt no physical "structure" per se. Rather, the stored data exist as a collection of bits having information about relationships between the ADOs. Yet this is the essence of electronic structure. In *Bernhart*, this court's predecessor noted:
>
> > There is one further rationale used by both the board and the examiner, namely, that the provision of new signals to be stored by the computer does not make it a new machine, i.e. it is structurally the same, no matter how new, useful and unobvious the result.... To this question we say that **if a machine is programmed in a certain new and unobvious way, it is physically different from the machine without that program; its memory elements are differently arranged**. The fact that these physical changes are invisible to the eye should not tempt us to conclude that the machine has not been changed.
>
> *Bernhart*, 417 F.2d at 1400 (emphasis added).
> More than mere abstraction, the data structures are specific electrical or magnetic structural elements in a memory.

Moreover, by the logic applied by the Final Action, an unprogrammed processor circuit would anticipate any claimed processor circuit that is programmed to perform a specific task because there would allegedly be no structural difference between the unprogrammed processor circuit and the programmed processor circuit. Processor circuits are naturally defined by their function, not by an apparatus type structure. Accordingly, contrary to assertions in the Final Action, the programmed operations in independent Claim 8 do recite structural differences over Santini.

Furthermore, to the extent that the rejections are based on the allegation that Santini is **capable** of performing the above recited functions and, therefore, discloses the claimed subject matter, the Final Action is also flawed. *See, for example, Final Official Action, page 3, second and third full paragraphs.* Appellant maintains that the standard for anticipation under Section 102 is not whether a circuit discussed in a reference is **capable** of performing operations that are claimed. Rather, a finding of anticipation **requires that there must be no difference between the claimed invention and the disclosure of the cited**

reference as viewed by one of ordinary skill in the art. *See Scripps Clinic & Research Foundation v. Genentech Inc.*, 927 F.2d 1565, 1576, 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Accordingly, the theoretical capabilities of the circuit in Santini cannot be the basis of a rejection under section 102.

Moreover, established case law provides that an assertion that the prior art is capable of some function is not sufficient without an explanation (from the Examiner) regarding **how** the prior art elements perform each claimed function even though the prior art is structurally different. For example, in *Ex Parte Tomoyuki Kida*, 1997 WL 33102864, *1 (BPAI 1997), the court held that:

> In the instant case, the examiner has not explained how the prior art elements might be capable of performing each of the claimed functions that appear at least in independent Claims 1, 6, and 9. **The assertion on page 4 of the Answer that the functions are "inherent" in the prior art because the prior art structures are capable of "performing algebraic calculations" is inconsistent with the law of our reviewing court**. See *In re Lowry*, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim limitations regarding organization of data in memory held to distinguish over prior art). See also *In re Alappat*, 33 F.3d 1526, 1545, 31 USPQ2d 1545, 1558 (Fed. Cir. 1994)(commenting that prior cases held that computer, once programmed, creates a new machine); *In re Noll*, 545 F.2d 141, 148, 191 USPQ 721, 726 (CCPA 1976) ("[The claimed invention] comprises physical structure, including storage devices and electrical components uniquely configured to perform specified functions through the physical properties of electrical circuits to achieve controlled results. Appellant's programmed machine is structurally different from a machine without that program.") (emphasis added).

Accordingly, to the extent that the Final Action based the rejection of independent Claim 8 on the rationale that Santini is "capable" of performing the claimed operations, the rejection is insufficient and should be withdrawn.

The Final Official Action also states in-part with respect to the pending claims:

> These recitations are intended use of the circuit and a recitation of intended use of the claimed invention must result in a structural difference between the claimed and the prior art in order to patentably distinguish the claimed invention form [sic] the prior art. *Final Official Action, pages 3-4.*

Respectfully, the "intended use" rationale relied on by the Final Action is incorrect for the same reasons described above, as functional claim language does impart structural distinctions. For example, *WMS Gaming, Inc. v. International Game Technology*, 184 F.3d 1339, 1348 (Fed. Cir. 1999), held that:

> **The structure of a microprocessor programmed to carry out an algorithm is limited by the disclosed algorithm. A general purpose computer, or microprocessor, programmed to carry out an algorithm creates "a new machine, because a general purpose computer in effect becomes a special purpose computer once it is programmed to perform particular functions pursuant to instructions from program software."** *In re Alappat*, 33 F.3d 1526, 1545, 31 USPQ2d 1545, 1558 (Fed.Cir.1994) (en banc); see *In re Bernhart*, 57 C.C.P.A. 737, 417 F.2d 1395, 1399-1400, 163 USPQ 611, 615-16 (CCPA 1969) ("[I]f a machine is programmed in a certain new and unobvious way, it is physically different from the machine without that program; its memory elements are differently arranged."). **The instructions of the software program that carry out the algorithm electrically change the general purpose computer by creating electrical paths within the device. These electrical paths create a special purpose machine for carrying out the particular algorithm.** [FN3]
>
> FN3. A microprocessor contains a myriad of interconnected transistors that operate as electronic switches. See Neil Randall, Dissecting the Heart of Your Computer, *PC Magazine*, June 9, 1998, at 254-55. The instructions of the software program cause the switches to either open or close. See id. The opening and closing of the interconnected switches creates electrical paths in the microprocessor that cause it to perform the desired function of the instructions that carry out the algorithm. See id. (emphasis added).

As discussed above, the recited operations performed by the claimed processor circuit do provide structural differences over Santini. In view of the above stringent standard under Section 102, Appellant respectfully submits that Santini does not disclose the detailed recitations of Independent Claim 8 for at least the reasons described above.

III. The rejection of Claim 9

A. Dependent Claim 9 is Patentable

As recited above, Claim 9 stands rejected under 35 U.S.C. § 103 over Santini Gazdzinski or Meyer. *Final Official Action, page 5.* Appellant respectfully submits

that Claim 9 is patentable for at least the reasons described above in reference to independent Claim 8.

IV. The rejection of Claims 10-13

A. Dependent Claims 10-13 are Patentable

As recited above, Claims 10-13 stand rejected under 35 U.S.C. § 103 over Santini in view of Crowley. *Final Official Action, page 5.* Appellant respectfully submits that Claims 10-13 are patentable for at least the reasons described above in reference to independent Claim 8.

V. The rejection of Claim 14

A. Dependent Claim 14 is Patentable

As recited above, Claim 14 stands rejected under 35 U.S.C. § 103 over Santini in view of Sheppard Jr. *Final Official Action, page 7.* Appellant respectfully submits that Claim 14 is patentable for at least the reasons described above in reference to independent Claim 8.

VI. The rejection of Claim 35

A. Dependent Claim 35 is Patentable

As recited above, Claim 35 stands rejected under 35 U.S.C. § 103 over Santini in view of Santini Jr. *Final Official Action, page 8.* Appellant respectfully submits that Claim 35 is patentable for at least the reasons described above in reference to independent Claim 8.

II. Conclusion

In light of the above, Appellant requests reversal of the rejections of the claims, allowance of the claims and passing of the application to issue.

It is not believed that an extension of time and/or additional fee(s) are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event, however, that an extension of time is necessary to allow consideration of this paper, such an extension is hereby petitioned for under 37 C.F.R. §1.136(a). Any additional fees believed to be due in connection with this paper may be charged to Deposit Account No. 50-0220.

Respectfully submitted,

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Audra Wooten

APPENDIX A

1.-7. (Canceled)

8. (Previously presented) A circuit for detecting biomolecules *in vivo*, the circuit comprising

an optical radiation source configured for *in vivo* use that emits first optical radiation;

an optical radiation detector configured for *in vivo* use that detects second optical radiation emitted by excited labeled binding molecules; and

a processor circuit, coupled to the optical radiation source and the optical radiation detector, wherein the processor circuit is configured to release fluorescently labeled antibodies selected to bind with predetermined Tumor Specific Antigens (TSAs),

the processor circuit is further configured to activate the *in vivo* optical radiation source after a predetermined first time interval after release of the fluorescently labeled antibodies, the predetermined first time interval selected to allow a first portion of the fluorescently labeled antibodies to bind with local available TSAs and a second portion of the fluorescently labeled antibodies to become remote from the circuit so that the first optical radiation excites the first portion of the fluorescently labeled antibodies bound with the local available TSAs and does not excite the second portion of the fluorescently labeled antibodies that become remote,

the processor circuit is further configured to sense a voltage generated by the *in vivo* optical radiation detector after a second predetermined time interval, the second predetermined time interval being after emission of the first optical radiation has ceased.

9. (Previously presented) A circuit according to Claim 8, wherein the optical radiation source comprises a laser.

10. (Original) A circuit according to Claim 8, wherein the optical radiation detector is selected from a group consisting of a phototransistor, a photodiode, and a photomultiplier.

11. (Original) A circuit according to Claim 8, wherein the first optical radiation has a first frequency and the second optical radiation has a second frequency.

12. (Original) A circuit according to Claim 11, wherein the first frequency is greater than the second frequency.

13. (Previously presented) A circuit according to Claim 8 further comprising:

an emission filter coupled to the optical radiation source; and

an absorption filter coupled to the optical radiation detector.

14. (Original) A circuit according to Claim 8, further comprising:

an inductor coupled to the processor, wherein the inductor provides power to the circuit in response to a power signal received from the *ex vivo* system.

15. (Original) A circuit according to Claim 8, wherein the circuit is on a platform having a diameter of about 2mm.

16. (Previously presented) A circuit according to Claim 8, wherein the signal is digitally encoded.

17. (Currently amended) A circuit according to Claim 8, wherein the circuit is on a platform coated with a biocompatible optical translucent layer.

18.-28. (Canceled)

29. (Previously presented) A circuit according to Claim 8 wherein the first and second optical radiation comprises first and second optical radiation at respective first and second wavelengths selected to promote transmission of the first and second optical radiation through a bio-fouling tissue on the optical radiation source and the optical radiation detector.

30. (Previously presented) A circuit according to Claim 8, wherein the circuit comprises an implantable circuit configured for *in vivo* implantation for at least six months.

31. (Previously presented) A circuit according to Claim 8 wherein the processor circuit is further configured to provide the signal for wireless transmission to the *ex vivo* system.

Claims 32-34 (Canceled).

35. (Previously presented) A circuit according to Claim 8 further comprising:

a piezoelectric circuit responsive to the processor circuit, wherein the piezoelectric circuit is configured to vibrate under control of the processor circuit to release the labeled binding molecules.

36. (Previously presented) A circuit according to Claim 8, wherein the processor circuit is further configured to control release of unlabled binding antibodies separate from the fluorescently labeled antibodies.

37. (Previously presented) A circuit according to Claim 36 wherein the processor circuit is further configured to release ~~of~~ the unlabled binding antibodies during a first time interval and to release the fluorescently labeled antibodies during a second time interval.

38. (Withdrawn) A circuit for detecting biomolecules *in vivo*, the circuit comprising:

an *in vivo* optical radiation source configured to emit first optical radiation;

a first *in vivo* optical radiation detector configured to detect the first optical radiation to provide an optical radiation source feed back signal;

a second *in vivo* optical radiation detector configured to detect second optical radiation emitted by excited labeled binding molecules; and

a processor circuit, coupled to the *in vivo* optical radiation source and the first and second *in vivo* optical radiation detectors, configured to change a level of the first optical radiation based on the optical radiation source feed back signal.

39. (Withdrawn) A circuit according to Claim 38 further comprising:

a circuit board having the processor circuit and, the first and second optical radiation detectors thereon, wherein the first and second optical radiation detectors are on opposing sides thereof.

40. (Withdrawn) A circuit for detecting biomolecules *in vivo*, the circuit comprising:

an *in vivo* optical radiation source configured to emit first optical radiation;

an *in vivo* optical radiation detector configured to detect second optical radiation emitted by excited labeled binding molecules; and

a processor circuit, coupled to the *in vivo* optical radiation source and the *in vivo* optical radiation detector, configured to operate in conjunction with the release of labeled binding molecules for binding with biomolecules associated with tumors for excitation by the first optical radiation and that receives an intensity signal associated with the intensity of the second optical radiation.

41. (Withdrawn) A circuit for detecting biomolecules *in vivo*, the circuit comprising

an *in vivo* optical radiation source configured to emit first optical radiation;

an apparatus configured to controllably release labeled binding molecules for excitation;

an *in vivo* optical radiation detector configured to detect second optical radiation emitted by excited labeled binding molecules; and

a processor circuit, coupled to the *in vivo* optical radiation source, the *in vivo* optical radiation detector, and the apparatus, the processor circuit configured to control the emission of the first optical radiation and to receive a signal associated with the intensity of the second optical radiation and configured to temporally control release of labeled binding molecules from the apparatus according to a predetermined time interval.

42. (Withdrawn) A circuit according to Claim 41 wherein the apparatus is in communication with a vibrator configured to vibrate responsive to control of the processor circuit

APPENDIX B – EVIDENCE APPENDIX

(NONE)

APPENDIX C – RELATED PROCEEDINGS

(NONE)